REMARKS

Reconsideration and allowance are respectfully requested.

Claims 32-41 are pending. In this response, claims 32, 33, 35, and 39 are amended for clarity. No new matter is added, and it is believed that none of the amendments narrows the scope of any of the pending claims.

The Examiner has objected to the description of the drawings. In this response, the specification has been amended to more accurately described Figures 1 and 2. No new matter is added.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 32-41 have been rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness, for: (i) the recitation of "wherein the Factor VIIa is recombinant human Factor VIIa" (claims 35 and 39); and (ii) the recitation of "substantially the same biological activity as authentic Factor VIIa" (claims 32 and 33). These rejections are respectfully traversed.

In this response, claims 35 and 39 have been amended to clarify that the Factor VIIa referred to is modified Factor VIIa that has been produced recombinantly. It is believed that these amendments are responsive to the Examiner's objections and that this basis for rejection has been overcome.

With respect to claims 32 and 33, in the present response the phrase "substantially the same biological activity as authentic Factor VIIa" has been deleted. The claim as amended requires subcutaneous administration of "an effective amount [of a modified Factor VII] for treating said disease [i.e., a disease affectable by Factor VIIa]". This clearly defines the type of biological activity that is provided by the modified Factor VIIa; accordingly, phrase that has been deleted is redundant.

For the above reasons, it is believed that these rejections have been overcome and may be withdrawn.

Double Patenting

Claims 32-41 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of U.S. Patent No. 6,310,183 (the "'183 patent") in view of Nicholaisen et al., U.S. Patent No. 5,580,560. The Examiner contends that the claims of the '183 patent encompass subcutaneous administration of modified Factor VIIa; that Nicholaisen et al. discloses modified Factor VIIa with increased half-life, and that it would have been obvious in view of the '183 patent to administer subcutaneously the modified Factor VIIa of Nicholaisen et al. This rejection is respectfully traversed.

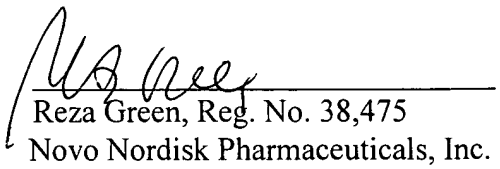
Subcutaneous administration of Factor VIIa as claimed in the '183 patent represents one means of prolonging the effective half-life of Factor VIIa, which may be due (at least in part) to the fact that Factor VIIa administered in this manner takes more time to percolate into the circulation and thereby reach its ultimate site(s) of action and/or clearance. The physical effect on Factor VIIa half-life due to subcutaneous administration would thus be expected to be distinct from a prolonged half-life secondary to a modification of the Factor VIIa molecule itself. Accordingly, it is not believed that Nicholaisen et al. is relevant to the present claims.

Nonetheless, to expedite prosecution a terminal disclaimer is attached herewith. It is respectfully submitted on that basis that this rejection has been overcome and should be withdrawn.

In view of the above amendments, remarks, and disclaimer, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: May 6, 2004



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